

K011480

MAY 24 2001

## II. 510(k) SUMMARY

Submitted by:

RICHTER RUBBER TECHNOLOGY Sdn. Bhd.  
Plot 33, Kuala Ketil Industrial State  
Kuala Ketil, Malaysia  
tel: 011 60 4 416 1668 ; fax: 011 60 4 416 1667 (dialed from USA)

Contact Person: Klaus Richter                      During USA Business hours, tel:  
Frank C. Sadlo, (502)-634-3221

Date Prepared: February 27, 2001

Proprietary Name: VIVA (TM)

Common Name: Latex Condom

Classification Name: Condom (21 CFR §884.5300)

Predicate Device: Latex Lubricated Condom  
510(k) #K 984392  
K 993781  
K 994095

Description of the Device: This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom is designed with an integral ring at the open end and a reservoir at the closed end to contain semen. VIVA (TM) condoms are designed to conform to established Standards including ASTM D 3492, ISO 4074 and EN 600.\*\*

Intended Use of the Device: This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases.)

Technological Characteristics: This condom has the same technological characteristics as the predicate condoms identified above. This condom is made of first grade natural rubber latex material using Richter Hi-Tech manufactured automatic dipping lines. The design of this condom is in conformance with WHO, ISO, EN 600, DIN and ASTM Latex Condom Standard D3492-97.\*\*

\*\*Richter Rubber Technology currently Manufactures and Sells "Standard-Sized" condoms which Conform to the ASTM Length and Width Standards. We have Manufactured for Sale condoms which do not meet the ASTM Length and Width Standards, in accord with United States Patent #5857466, to produce "condoms that actually fit" each individual user. Condoms "provided in a wide variety of sizes one of which best correlates to the needs of each particular user," (U.S. Patent #5857466) to provide maximum natural sensation and product safety.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

MAY 24 2001

Richter Rubber Technology Sdn. Bhd.  
c/o Mr. Frank C. Sadlo  
CEO  
Oceans Seven, International  
Box 32222  
LOUISVILLE KY 40232

Re: K011480  
Viva™ Latex Condom  
Dated: February 27, 2001  
Received: May 14, 2001  
Regulatory Class: II  
21 CFR §884.5300/Procode: 85 HIS

Dear Mr. Sadlo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

*Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR §884.5300 and §884.5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR §801.435. Therefore, an expiration date, supported by test data developed under the conditions specified in §801.435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, §801.435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, §801.435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in §801.435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

*for David G. Brogdon*  
Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

K 011480

**VII. INDICATIONS FOR USE STATEMENT**

510(k) Number: K011480

Device Name: VIVA (TM) Male Natural Rubber Latex Condom

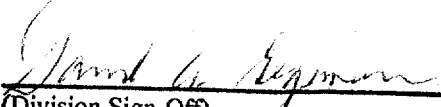
Indications For Use: The VIVA brand condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR §801.109)

OR Over-The-Counter Use ☒

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K011480